DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0362]

Draft Guidance for Industry on Stability Testing of Drug Substances and Drug Products; Availability; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending to December 8, 1998, the comment period for the draft guidance for industry entitled ''Stability Testing of Drug Substances and Drug Products.'' The draft guidance provides recommendations regarding the stability studies that should be performed to support new drug applications (NDA's), abbreviated new drug applications (ANDA's), investigational new drug applications (IND's), biologics license applications (BLA's), product license applications (PLA's), and supplements to these applications. FDA published a notice of availability of the draft guidance in the **Federal Register** of June 8, 1998 (63 FR 31224). FDA is taking this action in response to several requests for an extension.

DATES: Written comments on the draft guidance may be submitted by December 8, 1998. General comments on the draft guidance are welcome at any time.

ADDRESSES: Copies of the draft guidance for industry are available on the Internet at ''http://www.fda.gov/cder/guidance/index.htm''. Submit written requests for single copies of the draft guidance to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments are to be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Kenneth J. Furnkranz, Center for Drug Evaluation and Research (HFD–625), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855–2737, 301–827–5848.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of June 8, 1998 (63 FR 31224), FDA published a notice announcing the availability of a draft guidance for industry entitled ''Stability Testing of Drug Substances and Drug Products.'' The draft guidance provides recommendations regarding the stability studies that should be performed to support NDA's, ANDA's, IND's, BLA's, PLA's, and supplements to these applications. Interested persons were given until September 9, 1998, to submit written comments on the draft guidance.

On June 18, 1998, FDA received a letter from Perrigo requesting that the agency extend the comment period on the draft guidance 120 days. On June 29, 1998, FDA received a letter from Pharmaceutical Research and Manufacturers of America requesting that the agency extend the comment period on the draft guidance 90 days.

This draft guidance is long and complex and introduces a number of new issues. Therefore the agency has decided to extend the comment period on the draft guidance to December 8, 1998, to allow the public more time to review and comment on its contents.

Interested persons may, on or before December 8, 1998, submit to the Dockets Management Branch (address above) written comments on the draft guidance. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 12, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration publishes abstracts of information collection requests under review by the office of Management and Budget, in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance request submitted to OMB for review, call the HRSA Reports Clearance Office at (301) 443–1129. The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

Proposed Project: Evaluation of Health Care for the Homeless Program.—New—This is a request for approval to collect data to develop and test emergency department (ED) utilization rates as a measure of effectiveness of the Bureau of Primary Health Care's (BPHC) Health Care for the Homeless (HCH) program. The HCH Program is a Federal grant program authorized by section 330(h) of the Public Health Service Act. This program seeks to improve access by homeless individuals to primary health care and substance abuse treatment.

Data will be collected in five communities in which there are Health Care for the Homeless (HCH) grantees. Between 250–300 single homeless persons will be interviewed at soup kitchens in each of the five communities. The objective is a total sample of 1,350. There will be five categories of questions respondents will be asked: Emergency Room Visits, Inpatient Hospital Utilization, Outpatient Health Care Utilization, Health Status and Perceived Need for Health Care, and Demographics. Information from the study will be used in conjunction with data from ED records of homeless individuals with self reported ED use during the study period to determine whether particular ED visits should be considered ''appropriate or ''non-appropriate'.

The estimated reporting burden is as follows:

Type of report	Number of respondents	Minutes per response	Total burden hours
Individual	1,350	20	450